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10/679,642	10/06/2003	Henrik Bengtsson	6517.200-US	3938

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EXAMINER	
MACNEILL, ELIZABETH	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,642	BENGTSSON, HENRIK	
	Examiner	Art Unit	
	ELIZABETH R. MACNEILL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-25* is/are pending in the application.

4a) Of the above claim(s) *9-11,18-20,22,23 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12,14-17,21 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 9-11, 18-20, 22, 23, and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 19 April 2006. Claim 25, the external tubing, is shown in Fig 6 only.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7, 12,14-17,21 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Aceti et al (US 7,004,928).

Regarding claim 1, Aceti teaches a needle device (10) comprising: a mounting surface adapted for application to the skin of a subject, adhesive means (Fig 29b) arranged on the mounting surface for adhering the needle device to the skin of the subject, a plurality of needles (46), each needle comprising a distal pointed end adapted to penetrate the skin of the subject, wherein each needle has a first position in which the distal end is retracted relative to the mounting surface, and a second position in which the distal end

projects from the mounting surface, the needles being arranged such that at least one needle can be moved from its first to its second position or from its second to its first position with at least one other needle not performing the same movement. Figs 1-4. The device comprises a common fluid conduit means (234, Col 10 line 59), wherein a plurality of the needles are hollow having a distal and a proximal opening (44), the proximal opening being in fluid communication with the common fluid conduit means when the needle is in its second position.

Regarding claim 2, needle actuating means (22) are associated with a plurality of needles, the needle actuating means being operatable between a first actuating position and a second actuating position, whereby a first associated needle is moved from its first to its second position and a second associated needle is moved from its second to its first position.

Regarding claim 3, the needle actuating means are operatable between a plurality of actuating positions, each operation between actuating positions being associated with operation of a corresponding pair of needles between their first and second respectively second and first positions.

Regarding claim 4, the needle actuating means is operatable between an initial position, in which all associated needles are in their first position, and an actuating position, whereby a needle is moved from its first to its second position.

Regarding claim 5, the needle actuating means is operatable between an actuating position, in which an associated needle is in its second position, and an end position in which all associated needles are in their first position.

Regarding claim 6, each of the associated needles are connected to a needle carrier (266), the actuation means comprising moveable control means (268) in engagement with or operatable to come into engagement with the needle carriers, the position of the control means controlling operation of the needles between their respective first and/or second positions.

Regarding claim 7, the needle carriers are associated with biasing means (176) for moving the respective needle from its first to its second position by a force generated by the biasing means, release of the biasing means being controlled by movement of the control means.

Regarding claim 12, the device comprises means (teeth on 282) preventing a needle from being moved from its first to its second position more than once.

Regarding claim 14, the proximal opening of a hollow needle is not in fluid communication with the common fluid conduit means when the needle is in its first position.

Regarding claim 15, the device contains a reservoir ("pharmaceutical agent delivery microchannel") adapted to contain a liquid drug and comprising an outlet in fluid communication with the common fluid conduit means.

Regarding claim 16, the device contains expelling means (needle outlet and controller) for expelling a drug out of the reservoir and through the skin of the subject via the common fluid conduit means and a hollow needle.

Regarding claim 17, the common fluid conduit means comprises a fluid inlet means (44).

Regarding claim 21, the plurality of needles comprises at least two hollow infusion needles, the hollow infusion needles being arranged such that only one infusion needle can be positioned in the second position at a given time.

As to claim 24, see "For delivery of a drug or pharmaceutical agent, the drug is preferably fluid is stored in a compressible microchannel (e.g., a microchannel having a flexible cover). As the slider 268 moves towards the extended position it preferably presses the microneedle 214 into the skin or tissue. As the microneedle is inserted the slider can at least partially compressing microchannel 220 and forcing the fluid out through the conduit 242 and ultimately the microneedle 214 and into the skin or tissue."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al in view of Groth (WO 01/93927, cited by applicant)

Aceti teaches the device as above but fails to teach the sloped cam surface. Groth teaches a needle device wherein the control means comprises a cam surface (6) with a sloped portion, whereby movement of the sloped portion causes a needle to be moved from its second to its first position against the force of the biasing means (Fig 3 and 4).

One of ordinary skill in the art at the time the invention was made would have expected that substituting the cam surface of Groth for the moveable control means of Aceti to perform equally well, since they both perform the same function and are used to select and move individual needles.

Response to Arguments

Applicant's arguments filed 15 February 2008 have been fully considered but they are not persuasive. Applicant has argued that the fluid conduit means 234 are not equivalent with the claimed "common fluid conduit member." As noted by the applicant, Aceti discloses that the fluid conduit means 234 are described as follows: "once microneedle 214 is in the extended position, the proximal end of the microneedle 244 and fluidic capture site 280 interfaces with a microchannel 220. The fluidic capture site is formed with an opening that generally couples to a conduit 234 and ultimately microchannel 220 as discussed with respect to FIG. 3." The claimed limitations of the "common fluid conduit" are: a common fluid conduit member…a plurality of needles…having a proximal opening, the proximal opening being in fluid communication with the common fluid conduit member when the needle is in its second position." This is exactly the same as the disclosure of the conduit 243 by Aceti. The applicant appears to be arguing limitations that are not found in the claims. Applicant is arguing that the needles are in communication with the **same fluid conduit member and the same fluid source/inlet when in the second position**. This is not found in the claims.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767